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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,647	04/16/2001	Satoru Oi	2560USOP	2246

23115 7590 02/11/2005

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EXAMINER	
KIFLE, BRUCK	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 02/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,647	OI ET AL.	
	Examiner	Art Unit	
	Bruck Kifle, Ph.D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,16 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13, 16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's amendments and remarks filed 11/19/2004 have been received and reviewed. Claims 1-13, 16 and 17 are now pending in this application.

Information Disclosure Statement

No IDS filed on April 16, 2001 was found in the file.

Claim Rejections - 35 USC § 112

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) Regarding the definition of "B," Applicants point to page 12, lines 5-21 of the specification and regarding the substituents, Applicants point to page 12, line 22 – page 14, line 16. However, mere examples have been recited on these pages and Applicants cannot rely on these. The intended ring at "B" and its substituents need to be included in the claims to overcome this rejection. One skilled in the art should be able to say what the metes and bounds of the claims are. The basis of this rejection is the same as given in the previous office action and is incorporated herein fully by reference.

ii) Similarly, in support of the definition of R^1, Applicants point to the specification. However, the specification has language that is open ended. The basis of this rejection is the same as given in the previous office action and is incorporated herein fully by reference. The nature of the hydrocarbon, the atoms that make up the ring, which atoms are present and what kind of a ring (monocyclic, bicyclic, spiro, fused, bridged, saturated, etc.) is intended in heterocyclic and what kind of an acyl group is intended needs to be inserted in the claims.

iii) Similarly, the R^2 substituents of the amino group should be included in the claims.

iv) Again, the groups defined in page 19, line 7 – page 20, line 5 are exemplary. Applicants need to include the intended divalent group in the claims.

v) In "E", the definition of R^a and R^b is indefinite because the metes and bounds of the hydrocarbon group and the substituents are not known. These limitations have to be included in the claims.

vi) Similar to point iv) above the intended divalent groups of "G" and "L" should be included in the claims because the definition in the specification is open-ended.

vii) The substituents of "A", "X" and "Y" should also be included in the claims.

viii) The ring formed by R^2 and an atom on ring B needs to be specified in the claims.

ix) In claim 11 it is not known what the prodrug looks like. Arriving at a given prodrug is a research project. One skilled in the art cannot say what the prodrug of claim 11 looks like.

Applicants are reminded that although the claims are interpreted in light of the specification, critical limitations from the specification cannot be read into the claims (see, e.g., In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Ded. Cir. 1991)). Accordingly, without the recitation of all these critical limitations, the claims do not adequately define the instant invention.

The U.S. Court of claims held to this standard in Lockheed Aircraft vs. Unites States, 193 USPQ 449, "claims measure the invention and resolution of invention must be based on what is claimed."

The CCPA said "that invention is the subject matter defined by the claims submitted by the applicant." "We have consistently held that no applicant should have limitations of the

specification read into a claim where no express statement of the limitation is included in the claim" (In re Priest, 199 USPQ 11 at 15).

Therefore, Applicants need to indicate, in the claim, what is intended.

Claim 16 is under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for preventing or treating diabetes, obesity, diabetic complications or intractable diarrhea.

In evaluating the enablement question, several factors are to be considered. Note In re Wands, 8 USPQ2d 1400 and Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

1) The nature of the invention: The claim is drawn to preventing or treating diabetes, obesity, diabetic complications or intractable diarrhea.

2) The state of the prior art: There are no known compounds of similar structure, nor any somatostatin receptor function regulator which have been demonstrated to prevent or treat diabetes, obesity, diabetic complications or intractable diarrhea.

3) The predictability or lack thereof in the art: It is presumed in the prevention of the diseases claimed herein there is a way of identifying those people who may develop any kind of the disorders recited. There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disorders claimed herein.

4) The amount of direction or guidance present and 5) the presence or absence of working examples: There are no doses present to direct one to protect a potential host from the disorders cited, etc. There are no doses present for treatment of the disorders recited and there is no data present for the prophylaxis of these disorders.

6) The breadth of the claims: The claims are drawn to disorders that are not related and whose prevention is unknown. See for example, diabetic complications. These include gangrene and retinal detachment. There is no evidence that these compounds can treat, much less prevent, these disorders.

7) The quantity of experimentation need would be an undue burden to one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan for the many reasons stated above.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims.

The scope of uses embraced by the claim is not remotely enabled based solely on instant compounds ability to regulate a somatostatin receptor function.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This claim would read on regulating somatostatin receptor function *in vitro*, regulating somatostatin receptor function in

mammals with normal somatostatin receptor function or in asymptomatic mammals with up-regulated somatostatin receptor function. The specification fails to teach any benefit to be gained from such actions. Is extensive experimentation required on the part of a potential infringer to determine if his use of Applicants' regulator falls within the limitations of applicants' claim? *In re Kirk and Petrow*, 153 USPQ 48 (CCPA 1967). As the Supreme Court said in *Brenner v. Manson*, 148 USPQ at 696: "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." As U.S. Court of Customs and Patent Appeals stated *In re Diedrich* 138 USPQ at 130, quoting with approval from the decision of the board: "We do not believe that it was the intention of the statutes to require the Patent Office, the courts, or the public to play the sort of guessing game that might be involved if an applicant could satisfy the requirements of the statutes by indicating the usefulness of a claimed compound in terms of possible use so general as to be meaningless and then, after his research or that of his competitors has definitely ascertained an actual use for the compound, adducing evidence intended to show that a particular specific use would have been obvious to men skilled in the particular art to which this use relates."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle, Ph.D. whose telephone number is 571-272-0668. The examiner can normally be reached Tuesdays to Fridays between 8:30 AM and 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund J. Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bruck Kifle, Ph.D.
Primary Examiner
Art Unit 1624

BK
February 10, 2005